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| EXAMINER | |
|---|---|
| TALMAN, JAMES R | |
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| 3737 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/769,745 | SURESH ET AL. | |
| | Examiner | Art Unit | |
| | James R. Talman | 3737 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *30 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *411-416,422-423 and 889-978* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *411-416,422,423 and 889-978* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :4/22/2005;1/28/2005;11/2/2004;7/30/2004;7/27/2004.

## DETAILED ACTION

1. Receipt of a preliminary amendment on 4/5/2004 is acknowledged. Claims 1-410, 417-421, and 424-888 are cancelled. Claims 411-416, 422-423, and 889-978 are pending.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 411-416, 422, 423, 890-920, are rejected under 35 U.S.C. 103(a) as being unpatentable over Halmann et al (US5151856) in view of Sheehan et al (US5601084).

As per claims 411, 415, and 416, and 890, Halmann et al discloses assessing a state of human heart tissue, comprising: providing to a computer system (computer graphic facilities, column 3, line 23) a plurality of images of heart tissue (imaging device generating a plurality of two-dimensional sections of a mammalian heart, column 3, lines 28-29), creating a model of at least a portion of an endocardial wall of a left ventricle of the heart (generate a three-dimensional model, column 3, lines 34-35; left ventricle, column 4, line 54); and assessing a movement of a-one or more parts of the endocardial wall model, including wall thickness variation (myocardial function...wall thickening, wall thinning, or wall motion, column 2, paragraph 2); and comparing the

movement to a predetermined standard to assess a state of the heart (normal heart...electronically comparing...model with the stored models, column 3, lines 54-61). Furthermore, Halmann discloses dynamic imaging of the heart (animation, e.g. to show the beating heart...cage model, column 2, lines 39-59), and therefore the model comprises the left ventricle in at least an end-systolic and an end-diastolic state. Halmann et al does not explicitly disclose assessing a movement of one or more parts of the endocardial wall model between the end-systolic state and the end-diastolic state. In the same field of endeavor (cardiac imaging) and solving the same problem (determing cardiac wall motion), Sheehan et al discloses assessing a movement of one or more parts of the endocardial wall model between the end-systolic state and the end-diastolic state (The modeling data are preferably produced for a plurality of times during a cardiac cycle, including at an end systole and at an end diastole. Column 3, lines 1-3; cardiac parameters for the heart preferably include at least one of a range of motion for a wall of the heart, column 3, line 53-55) using normals associated with the parts (412, 420). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to assess movement of one or more parts of the endocardial wall model between the end-systolic state and the end-diastolic state, because these two states correspond to the minimum and maximum volumes, respectively of the left ventricle, thereby providing the largest change in wall motion between any two points of the cardiac cycle, as taught by Sheehan et al (column 9, paragraph 2).

As per claim 412, and as applied to claim 411 above, Halmann et al discloses all the elements of the claimed invention except that it does not explicitly disclose

computing an average. In the same field of endeavor (cardiac imaging) and solving the same problem (determing cardiac wall motion), Sheehan et al discloses computing an average (a standard or average cardiac template, column 2, line 54). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to compute an average for the standard reference, because a single heart could be significantly different from the vast majority of hearts and would be a poor standard.

As per claims 413 and 414, and as applied to claim 411 above, Halmann et al further discloses displaying the state of the heart visually within the model (model which can be shaded or color coded to indicate...dysfunction, see abstract), clearly encompassing the use of a color gradient, which is extremely old and well known in the art.

As per claims 422 and 423, and as applied to claim 411 above, Halmann et al discloses all the elements of the claimed invention except that it does not explicitly disclose determining a number of parts in which the movement of each part is greater than a range from the predetermined standard and dividing the number of parts by a total number of parts. In the same field of endeavor (cardiac imaging) and solving the same problem (determing cardiac wall motion), Sheehan et al discloses determining parts that exceed the standard by a range (units of standard deviations form the mean of a normal reference population, column 13, lines 19-20) and normalizing the result to the total number of parts (normalized by heart chamber size, column 13, line 22).

As per claims 891 and 892, and as applied to claim 411 above, Hallman et al further discloses computing points and a plurality of points (boundary curves...32x32x32 voxel space, column 4 lines 43-45).

As per claims 893-896, 898-902, 904, 906, 907, and 909-914, and as applied to claim 411 above, Halmann et al further discloses displaying kinetic properties of heart tissue (mechanical degradation of certain zones of the heart, column 4, line 7), which mechanical degradation information can be used to assess normal, or non-viable tissue, end-diastolic volume, and/or transmurality and thereby indicate the need for revascularization, ventricular reconstruction, or mitral-valve repair, all of which are well known surgical procedures.

As per claims 897, 903, and 905, Halmann et al discloses all the elements of the claimed invention except that it does not explicitly disclose defining values by being more or less than two standard deviations from the standard. In the same field of endeavor (cardiac imaging) and solving the same problem (determing cardiac wall motion), Sheehan et al discloses determining parts that exceed the standard by a certain number of standard deviations (units of standard deviations form the mean of a normal reference population, column 13, lines 19-20). The choice of two standard deviations for the boundary is an obvious design choice that is not given patentable weight.

As per claim 908, and as applied to claim 411 above, Hallman et al further discloses a 3-D model (3-D shapes, column 4, line 45).

As per claims 915 and 916, and as applied to claim 411 above, Hallman et al discloses all the elements of the claimed invention except that it does not explicitly disclose calculating ejection fractions and basing diagnoses thereon. Sheehan et al discloses calculating ejection fractions (ejection fractions, column 19, line 1; Figure 26). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to calculate ejection fractions using the method of Sheehan et al because they can be used to diagnose cardiac pathologies indicating the need for procedures such as ventricular reconstruction as is well known in the art. The exact number used to define the threshold of normal/abnormal ejection fractions is an obvious design choice and is not given patentable weight.

As per claims 917-920, and as applied to claim 411 above, Halmann et al further discloses assessing valvular diseases (valvular diseases, column 3, line 65), but does not explicitly disclose locating of papillary muscle or mitral valve on the images. In the same field of endeavor (cardiac imaging) and solving the same problem (determing cardiac wall motion), Sheehan et al discloses locating of the papillary muscles (74, 344; papillary muscle intersections, Figure 26) and mitral valves (mitral valve structure, column 9, lines 11-12). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to locate the positions of papillary muscles and mitral valves using the method of Sheehan et al because this information can be used to diagnose valvular disease. Furthermore, defective mitral valves are a well-known cause of regurgitation.

4. Claim 889 is rejected under 35 U.S.C. 103(a) as being unpatentable over Halmann et al (US5151856) in view of Sheehan et al (US5601084) and further in view of Kramer et al (US Patent Application Publication 2004/0015081).

As per claim 889, and as applied to claim 411 above, the Halmann et al/Sheehan et al combination discloses all the elements of the claimed invention except that it does not explicitly disclose assessing movement towards a centerline of the heart. In the same field of endeavor (cardiac diagnosis using medical imaging), Kramer et al discloses assessing movement towards a centerline of the heart (centerline method, paragraph 41). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to assess movement relative to the centerline of the heart because this method has been shown to reduce interobserver variability in the delineation of endocardial boundaries, as taught by Kramer et al (paragraph 41).

5. Claims 921-935, 937-963, and 965-978 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halmann et al (US5151856) in view of Kramer et al (US Patent Application Publication 2004/0015081).

As per claim 921, Halmann et al discloses a method of assessing a state of a heart, comprising: providing a plurality of images of a heart (heart scans...MRI, CT, cine-CT... ultrasound, column 1, lines 66-68), wherein the plurality of images are taken over a selected period of time (cine-CT, col 1 ln 68; animation, e.g. to show the beating heart, col 2 lns 43-44); dividing the images of the heart into a plurality of regions of the heart (edge detection, col 3 ln 33; boundary curves, col 4 lns 37-48), wherein each of the regions corresponds between each of the images; assessing at least one property

of a ventricular boundary in each of the regions of the heart (wall motion, col 3 ln 13); and comparing each of the assessed properties to a normal range for each region of the heart, wherein the normal range is assessed from one or more healthy hearts (normal heart...electronically comparing...model with the stored models, column 3, lines 54-61). Halmann et al does not disclose assigning regions as dysynchronous or not based on the image data. In the same field of endeavor (cardiac diagnosis using medical imaging), Kramer et al discloses assessing regional dysnchrony quantitatively based on wall motion in medical images (A phase analysis technique provides for quantification of regional wall motion asynchrony from endocardial border contours generated from two-dimensional echocardiographic ventricular images. The technique produces results including a degree of radial ventricular asynchrony in heart failure patients with ventricular conduction delay to predict a magnitude of contractile function improvement with pacing therapy, paragraph 7). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to detect dysynchrony in the wall motion images of Halmann et al using the technique of Kramer et al, because dysynchronous contraction of the right and left ventricles is a well known cause of congestive heart failure, as taught by Kramer et al (paragraph 4).

As per claim 922, and as applied to claim 921 above, Halmann et al further discloses a computer system automatically performing the calculations (computerized analysis, column 1, line 65).

As per claims 923 and 926, and as applied to claim 921 above, Halmann et al further discloses creating a 3-D model of the heart from the images (generate a three-dimensional model, column 3, lines 34-35; left ventricle, column 4, line 54).

As per claim 924, and as applied to claim 923 above, Halmann et al further discloses creating a plurality of models (cine-CT... cage model, column 2, lines 52-58).

As per claim 925, and as applied to claim 924 above, Halmann et al discloses all the elements of the claimed invention except that it does not disclose assessing a dysynchronous. In the same field of endeavor (cardiac diagnosis using medical imaging), Kramer et al discloses assessing the dysynchronous index (A phase analysis technique provides for quantification of regional wall motion asynchrony, paragraph 4). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to assess the dysynchronous index using the plurality of models because it would allow one to calculate a moving average of the dysynchrony in order to predict the potential benefit of therapy for the patient, as taught by Kramer et al (486, Figure 4).

As per claims 927 and 928, and as applied to claim 921 above, Hallman et al further discloses computing points and a plurality of points (boundary curves...32x32x32 voxel space, column 4 lines 43-45).

As per claim 929, and as applied to claim 921 above, Hallman et al further discloses a selected period of time comprising a cardiac cycle (animation, e.g. to show the beating heart...cage model, column 2, lines 39-59).

As per claims 930-932, and as applied to claim 921 above, Hallman et al further discloses assessing wall thickness and wall motion, which inherently includes torsion because it is well known that the heart undergoes torsion when beating (myocardial function...wall thickening, wall thinning, or wall motion, column 2, paragraph 2).

As per claims 933-935, and as applied to claim 921 above, Hallman et al discloses all the elements of the claimed invention except that it does not disclose defining a normal range as a certain number of standard deviations away from the mean. In the same field of endeavor (cardiac diagnosis using medical imaging), Kramer et al discloses defining a normal range as a certain number of standard deviations away from the mean ( Continuous data are expressed in the text as the mean value .+-. standard deviation (SD), paragraph 62). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to measure ranges in terms of the number of SD's from a mean, because this is a well known way of measuring statistical spread, and would be a valid way of measuring the departure of a heart's properties from those of a healthy heart, assuming that the mean is calculated based on a statistically significant number of healthy hearts. Furthermore, the precise number of SD's to use is an obvious design choice and is not given patentable weight.

As per claim 937, and as applied to claim 921 above, Hallman et al discloses all the elements of the claimed invention except that it does not disclose assessing if the heart requires intervention based on the dysynchronous index. In the same field of endeavor (cardiac diagnosis using medical imaging), Kramer et al discloses assessing if the heart requires intervention based on the dysynchrony of the heart (therapy decision

module, 489; Figure 4). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to assess if the heart requires intervention based on the dysynchrony of the heart, as taught by Kramer et al, because it would avoid needless surgical intervention.

As per claims 938, 939, 941, 943, and 945, and as applied to claim 921 above, Halmann et al further discloses displaying kinetic properties of heart tissue (mechanical degradation of certain zones of the heart, column 4, line 7), which mechanical degradation information can be used to identify hyper-kinetic, akinetic, normal, and/or diskinetic tissue.

As per claims 940, 942, and 944, and as applied to claim 921 above, Hallman et al discloses all the elements of the claimed invention except that it does not disclose defining degrees of mechanical degradation based on a certain number of standard deviations away from the predetermined standard. In the same field of endeavor (cardiac diagnosis using medical imaging), Kramer et al discloses defining a normal range as a certain number of standard deviations away from the predetermined standard (Continuous data are expressed in the text as the mean value +/- standard deviation (SD), paragraph 62). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to measure ranges in terms of the number of SD's from a predetermined standard (mean), because this is a well known way of measuring statistical spread, and would be a valid way of measuring the departure of a heart's properties from those of a healthy heart, assuming that the mean is calculated based on a statistically significant number of healthy hearts. Furthermore,

the precise number of SD's to use is an obvious design choice and is not given patentable weight.

As per claim 946, and as applied to claim 938 above, Halmann et al discloses all the elements of the claimed invention except that it does not explicitly disclose assessing movement towards a centerline of the heart. In the same field of endeavor (cardiac diagnosis using medical imaging), Kramer et al discloses assessing movement towards a centerline of the heart (centerline method, paragraph 41). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to assess movement relative to the centerline of the heart because this method has been shown to reduce inter-observer variability in the delineation of endocardial boundaries, as taught by Kramer et al (paragraph 41).

As per claims 947 and 948, Halmann et al further discloses a computer system automatically performing the calculations (computerized analysis, column 1, line 65), which inherently includes a CPU and memory with stored programs. Furthermore, a carrier medium for storing program instructions is notoriously old and well known in the art. Therefore, the Halmann et al/Kramer et al combination, as applied to claim 921 above, discloses all the elements of the claimed inventions.

As per claims 949, 975, and 976, Halmann et al discloses a method of assessing a state of a heart, comprising: providing a plurality of images of a heart (heart scans...MRI, CT, cine-CT... ultrasound, column 1, lines 66-68), wherein the plurality of images are taken over a selected period of time (cine-CT, col 1 ln 68; animation, e.g. to show the beating heart, col 2 lns 43-44); dividing the images of the heart into a plurality

of regions of the heart (edge detection, col 3 ln 33; boundary curves, col 4 lns 37-48), wherein each of the regions corresponds between each of the images; assessing at least one property of a ventricular boundary in each of the regions of the heart (wall motion, col 3 ln 13); and comparing each of the assessed properties to a normal range for each region of the heart, wherein the normal range is assessed from one or more healthy hearts (normal heart...electronically comparing...model with the stored models, column 3, lines 54-61). Halmann et al does not disclose assigning regions as dysynchronous or not based on the image data and does not disclose providing a template for placement of one or more ventricular pacing leads based on the dysynchrony.

In the same field of endeavor (cardiac diagnosis using medical imaging), Kramer et al discloses assessing regional dysnchrony quantitatively based on wall motion in medical images (A phase analysis technique provides for quantification of regional wall motion asynchrony from endocardial border contours generated from two-dimensional echocardiographic ventricular images. The technique produces results including a degree of radial ventricular asynchrony in heart failure patients with ventricular conduction delay to predict a magnitude of contractile function improvement with pacing therapy, paragraph 7). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to detect dysynchrony in the wall motion images of Halmann et al using the technique of Kramer et al, because dysynchronous contraction of the right and left ventricles is a well known cause of congestive heart failure, as taught by Kramer et al (paragraph 4).

In the same field of endeavor (cardiac diagnosis using medical imaging), Kramer et al discloses providing a template for placement of one or more ventricular pacing leads based on the dysynchrony (pacing site, paragraph 28; Figure 14). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide a template for placement of one or more ventricular pacing leads based on the dysynchrony because it is well known that there is an optimal placement location of pacing leads, as taught by Kramer et al (paragraph 51).

As per claims 950-963 and 965-974, see claims 922-935 and 937-946, respectively, above.

As per claims 977 and 978, Halmann et al further discloses a computer system automatically performing the calculations (computerized analysis, column 1, line 65), which inherently includes a CPU and memory with stored programs. Furthermore, a carrier medium for storing program instructions is notoriously old and well known in the art. Therefore, the Halmann et al/Kramer et al combination, as applied to claim 949 above, discloses all the elements of the claimed inventions.

6. Claims 936 and 964 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halmann et al (US5151856) in view of Kramer et al (US Patent Application Publication 2004/0015081) and further in view of Watson et al (US4777962).

As per claims 936 and 964, and as applied to claims 921 and 949 above, the Halmann et al/Kramer et al combination discloses all the elements of the claimed invention except that it does not disclose computing a dysynchronous index wherein the dysynchronous index comprises a number of dysynchronous regions divided by a total

number of regions in the plurality of regions. Solving the same problem (assessing synchronicity of various anatomical regions that nominally are supposed to move in unison), Watson et al discloses a dysynchronous index (index...synchronous or asynchronous, columns 3-4, bridging), consisting of a ratio of a regional (compartmental) displacement to a total number of regions (tidal volume). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to define a dysynchrnous index consisting of the number of dysynchronous regions divided by a total number of regions because it would normalize the measurement to the size of the patient's heart, thereby providing a number that could be used to make relative comparisons of dysynchrony between patients.

***Conclusion***

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure and is cited on the attached list of references.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James R. Talman whose telephone number is 571-270-3029. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

James R Talman
Examiner
Art Unit 3737

Jrt

BRIAN L. CASLER
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